

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: H. Michael SHEPARD
Title: METHODS FOR TREATING
THERAPY-RESISTANT
TUMORS

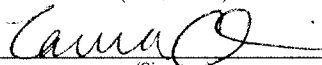
Appl. No.: 10/048,033

International Filing Date: 7/21/2000
371(c) Date:

Examiner: Crane, Lawrence E.

Art Unit: 1623

Confirmation Number: 2767

CERTIFICATE OF ELECTRONIC TRANSMISSION I hereby certify that this paper is being electronically transmitted to the United States Patent and Trademark Office, Alexandria, Virginia via EFS-Web on the date below.
Laura Davis (Printed Name)
 (Signature)
August 30, 2007 (Date of Transmission)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR

§1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

RELEVANCE OF EACH DOCUMENT

U.S. Patent Reference #1 (6,589, 941) is the equivalent of foreign-language reference #15 (WO 96/23506). An English translation of the foreign-language document is not readily available. However, the absence of such translation does not relieve the PTO from its duty to consider the submitted foreign language document (37 CFR §1.98 and MPEP §609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

FEE

Fees in the amount of \$180.00 in accordance with 37 CFR §1.17(p) to cover the fee associated with an information disclosure statement under 37 CFR §1.97(c) are being paid by credit card via EFS-Web.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date Aug. 30, 2007

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By Antoinette F. Konski

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Attorney for Applicant
Registration No. 34,202

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: August 30, 2007 <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/048033
				Filing Date	7/21/2000
				First Named Inventor	H. Michael Shepard
				Art Unit	1623
				Examiner Name	Crane, Lawrence E.
				Attorney Docket Number	060925-0601

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	P1	6,589,941	Fahrig et al.	07-08-2003	
	P2	6,599,499	Rosen et al.	07-29-2003	
	P3	6,677,314	Kleckner et al.	01-13-2004	
	P4	6,677,315	Kleckner et al.	01-13-2004	
	P5	6,682,715	Kleckner et al.	01-27-2004	
	P6	6,683,045	Kleckner et al.	01-27-2004	
	P7	6,683,061	Shepard et al.	01-27-2004	
	P8	6,703,374	Kleckner et al.	03-09-2004	
	P9	2002/0022001	Kleckner et al.	02-21-2002	
	P10	2002/0034473	Kleckner et al.	03-21-2002	
	P11	2002/0119094	Kleckner et al.	08-29-2002	
	P12	2002/0165199	Kleckner et al.	11-07-2002	
	P13	2003/0049201	Kleckner et al.	03-13-2003	
	P14	2003/0095921	Kleckner et al.	05-22-2003	

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Application Document	Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Serial Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	F15	WO 96/23506	08-08-1996	Fraunhofer Society for the Promotion of Applied Research E.V. (English Abstract)		

Examiner Signature	Date Considered
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Attorney Docket Number	060925-0601					
Sheet	2	of	5			

NON PATENT LITERATURE DOCUMENTS				
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	D16	BALZARINI et al. "Highly Selective Cytostatic Activity of (E)-5-(2-Bromovinyl)-2'-deoxyuridine Derivatives for Murine Mammary Carcinoma (FM3A) Cells Transformed with the Herpes Simplex Virus Type 1 Thymidine Kinase Gene" <i>Molecular Pharmacology</i> (1985) 28:581-587		
	D17	BALZARINI et al. "The cytostatic activity of 5-(1-azidovinyl)-2'-deoxyuridine (AzVDU) against herpes simplex virus thymidine kinase gene-transfected FM3A cells is due to inhibition of thymidylate synthase and enhanced by UV light ($\lambda = 254$ nm) exposure" <i>FEBS Lett.</i> 373:41-44 (1995)		
	D18	BARBATO et al. "Synthesis of bridged pyrimidine nucleosides and triazo [4, 3-c] pyrimidine nucleoside analogues" <i>Nucleosides & Nucleotides</i> 8(4):515-528 (1989)		
	D19	BATHE et al. "Increased thymidylate synthase gene expression in liver metastases from colorectal carcinoma: implications for chemotherapeutic options and survival" <i>Cancer J. Sci. Am.</i> 5(1):34-40 (1999)		
	D20	BIBLE et al. "Cytotoxic synergy between flavopiridol (NSC 649890, L86-8275) and various antineoplastic agents: the importance of sequence of administration" <i>Cancer Res.</i> 57(16):3375-80 (August 15, 1997)		
	D21	BRONZERT, D.A. "Purification and Properties of Estrogen-responsive Cytoplasmic Thymidine Kinase from Human Breast Cancer" <i>Can. Res.</i> (Feb. 1981) 41:604-610		
	D22	CASS et al. "Recent advances in the molecular biology of nucleoside transporters of mammalian cells" <i>Biochem. Cell Biol.</i> 76(5):761-770 (1998)		
	D23	CHOU and TALALAY, "Quantitative analysis of dose-effect relationships: the combined effects of multiple drugs or enzyme inhibitors" <i>Adv. Enzyme Regul.</i> 22:27-55 (1984)		
	D24	CORDON-CARDO and PRIVES "At the crossroads of inflammation and tumorigenesis" <i>J. Exp. Med.</i> 190(10):1367-1370 (November 15, 1999)		
	D25	COSTI et al. "Phthalein derivatives as a new tool for selectivity in thymidylate synthase inhibition" <i>J. Med. Chem.</i> 42(12):2112-2124 (1999)		
	D26	COSTI, et al. "Thymidylate Synthase Inhibition: A Structure-Based Rationale for Drug Design" <i>Medical Research Review</i> 18(1):21-42 (1998)		
	D27	CURT "Cancer drug development: new targets for cancer treatment" <i>Oncologist</i> 1(3):II-III (1996)		

Examiner Signature	Date Considered
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/048033
				Filing Date	7/21/2000
Date Submitted: August 30, 2007 (use as many sheets as necessary)				First Named Inventor	H. Michael Shepard
				Art Unit	1623
Sheet 3 of 5				Examiner Name	Crane, Lawrence E.
				Attorney Docket Number	060925-0601

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶	
	D28	DeCLERCQ et al. "Antiviral Activity of Novel Deoxyuridine Derivatives" Current Chemotherapy: Proceedings of the International Congress of Chemotherapy 1:352-354 (September 18, 1978)		
	D29	DeCLERCQ "Antiviral Activity Spectrum and Target of Action of Different Classes of Nucleoside Analogues" Nucleosides & Nucleosides 13(6&7):1271-1295 (1994)		
	D30	DeCLERCQ "In search of a selective antiviral chemotherapy" Clin. Micro. Review 10(4):674-693 (October 1997)		
	D31	DRAKE et al. "Resistance to Tornudex (ZD1694): Multifactorial in Human Breast and Colon Carcinoma Cell Lines" Biochem. Pharmacol. 51(10):1349-1355 (1996)		
	D32	FARROW et al. "Synthesis and biological properties of novel phosphotriesters: A new approach to the introduction of biologically active nucleotides into cells" J. Med. Chem. 33(5):1400-1406 (1990)		
	D33	GREM "Biochemical modulation of fluorouracil by dipyridamole: preclinical and clinical experience" Semin Oncol. 19(2 Suppl 3):56-65 (April 1992)		
	D34	GRIENGL et al. "Phosphonoformate and phosphonoacetate derivatives of 5-substituted 2'deoxyuridines: Synthesis and antiviral activity" J. Med. Chem. 31(9):1831-1839 (1988)		
	D35	HENGSTSCHLAGER, M. and E. WAWRA "Cytofluorometric determination of thymidine kinase activity in a mixture of normal and neoplastic cells" Br. J. Cancer (1993) 67:1022-1025		
	D36	JOHNSTON et al. "Thymidylate synthase gene and protein expression correlate and are associated with response to 5-fluorouracil in human colorectal and gastric tumors" Cancer Res. 55:1407-1412 (1995)		
	D37	KOMAKI et al. "Difference in thymidylate synthetase activity in involved nodes compared with primary tumor in breast cancer patients" Breast Cancer Res. Treat. 35(2):157-162 (1995)		
	D38	LEICHMAN "Thymidylate synthase as a predictor of response" Oncol. 12(8Suppl.6):43-47 (August 1998)		
	D39	LIBRA, et al. "Thymidylate synthase mRNA levels are increased in liver metastases of colorectal cancer patients resistant to fluoropyrimidine-based chemotherapy" BMC Cancer 4:11 (2004)		
	D40	LIVINGSTON et al. "Studies with tetrahydrohomofolate and thymidylate synthetase from amethopterin-resistant mouse leukemia cells" Biochem. 7(8):2814-2818 (1968)		

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	D41	LOOK et al. "Increased thymidine kinase and thymidylate synthase activities in human epithelial ovarian carcinoma" Anticancer Res. 17:2353-2356 (1997)		
	D42	MIAO et al. "A Stepwise One Pot Synthesis of Alkyl Thiophosphoramidate Derivatives of Nucleosides" Synthetic Communications 32(8):1159-1167 (2002)		
	D43	NICULESCU-DUVAZ et al. "Gene-directed enzyme prodrug therapy: A review of enzyme/prodrug combinations" Expert Opin. Invest. Drugs 6(6):685-703 (1997)		
	D44	PATTERSON et al. "Thymidine phosphorylase moderates thymidine-dependent rescue after exposure to the thymidylate synthase inhibitor ZD1694 (tomudex) in vitro" Cancer Res. 58:2737-2740 (1998)		
	D45	PEDERSEN-LANE et al. "High-level expression of human thymidylate synthase" Protein Expression and Purification 10:256-262 (1997)		
	D46	ROONEY et al. "Comparative Genomic Hybridization Analysis of Chromosomal Alterations Induced by the Development of Resistance to Thymidylate Synthase Inhibitors" Cancer Res. 58:5042-5045 (November 15, 1998)		
	D47	SMITH et al. "Response to doxorubicin of cultured normal and cancerous human mammary epithelial cells" J. Nat'l Cancer Inst. 74(2):341-347 (1985)		
	D48	TOUROUTOGLU et al. "Thymidylate synthase inhibitors" Clin. Cancer Res. 2(2):227-243 (February 1996)		
	D49	TSAVARIS et al. "Multimodal biochemical modulation of 5-fluorouracil activity in advanced colorectal cancer with allopurinol, folinic acid and dipyrindamol" J. Chemother. 2(2):123-126 (1990)		
	D50	van LAAR "Therapeutic efficacy of fluoropyrimidines depends on the duration of thymidylate synthase inhibition in the murine colon 26-B carcinoma tumor model" Clin. Cancer Res. 2(8):1327-1333 (1996)		
	D51	van TRIEST et al. "Thymidylate synthase level as the main predictive parameter for sensitivity to 5-fluorouracil, but not for folate-based thymidylate synthase inhibitors, in 13 nonselected colon cancer lines" Clin. Cancer Res. 5(3):643-654 (1999)		
	D52	VLAYKAVA et al. "Increased Thymidylate Synthase Gene Expression in Metastatic Melanoma" Oncology 54:146-152 (1997)		
	D53	WHALEN et al. "Human glutathione S-transferases" Seminars in Liver Disease 18(4):345-358 (1998)		

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	D55	WILLSON et al. "Phase I Clinical Trial of a Combination of Dipyridamole and Acivicin Based Upon Inhibition of Nucleoside Salvage" Cancer Res. 48:5585-5590 (October 1, 1998)		
	D56	WOLFE et al. "Antibody-directed enzyme prodrug therapy with the T268G mutant of human carboxypeptidase A1: in vitro and in vivo studies with prodrugs of methotrexate and the thymidylate synthase" Bioconjugate Chemistry 10(1):38-48 (1999)		

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